IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA,)))
Plaintiff,)
) Civil Action No. 2:15-CV-06133-WB
V.)
ELI LILLY AND COMPANY,))
IMCLONE LLC and)
BRISTOL MYERS SQUIBB COMPANY,)
Defendants.)
	_)

PLAINTIFF THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS CLAIMS 32-40 OF U.S. PATENT NO. 7,625,558

Defendants Eli Lilly and Company, ImClone LLC and Bristol Myers Squibb Company (collectively, "Defendants") have moved pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss allegations of infringement relating to Claims 32-40 of U.S. Patent No. 7,625,558 ("the '558 patent"). According to Defendants, these claims are invalid for failing to meet the requirements of 35 U.S.C. § 112, ¶ 5. Plaintiff, The Trustees of the University of Pennsylvania ("Penn"), for the reasons set forth below, respectfully requests that the Court deny Defendants' Motion in its entirety.

I. INTRODUCTION

Defendants move to dismiss infringement allegations for Claims 32-40 of the '558 patent solely on the grounds of technical, easily remedied, claim dependency errors. Claims 32-40 are drafted in the form of "multiple dependent claims." A multiple dependent claim is one that

refers to more than one other preceding claim. In their current form, however, Claims 32-40 are improperly written as multiple dependent claims that expressly rely on other multiple dependent claims. While this type of claim drafting is not allowed under 35 U.S.C. § 112, ¶ 5, where the mistake and the corresponding correction are obvious—as they are here—the Court has the authority to correct the patent.

The appropriate avenue for resolving this issue is not Defendants' motion on the pleadings, but rather is the Court's claim construction process. During an infringement suit, the Court has the authority to interpret a patent and correct certain obvious errors. Thus, rather than summarily invalidating these claims at the outset of the case, this Court should correct the dependency errors during claim construction.

II. LEGAL STANDARDS

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a district court should conduct a two part analysis: First, it should separate the factual and legal elements of a claim and accept all of the well-pled facts as true. Second, it should determine whether the factual allegations "are sufficient to show that the plaintiff has a plausible claim for relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009). If so, then the court should deny the motion to dismiss. *Id.* A claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted). "This 'plausibility' determination will be "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Fowler*, 578 F.3d at 211 (citing *Iqbal*, 556 U.S. at 663-664).

A multiple dependent claim is a dependent claim that refers to more than one other preceding claim. Multiple dependent claims are allowed under 35 U.S.C. § 112, subject to the limitations enumerated in 35 U.S.C. § 112, ¶5. Specifically, a multiple dependent claim shall refer to other claims in the alternative only and "shall not serve as a basis for any other multiple dependent claim." 35 U.S.C. § 112, ¶ 5.1

"It is well-settled law that, in a patent infringement suit, a district court may correct an obvious error in a patent claim." *CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353, 1358 (Fed. Cir. 2011) (citing *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 442 (1926)). District courts may correct a patent claim where: (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification, and (2) the prosecution history does not suggest a different interpretation of the claim. *Intermec Techs*.

Corp. v. Palm Inc., 811 F. Supp. 2d 973, 984 (D. Del. 2011) (citing *Ultimax Cement Mfg. Corp.* v. CTS Cement Mfg. Corp., 587 F.3d 1339, 1353 (Fed. Cir. 2009)). Accordingly, "determining whether an error in a patent is correctable by the court is a two-step process: First, the court must find that the error is evident on the face of the patent; second, the specification and claims, as well as the prosecution history, are to be consulted in order to ascertain whether there is only a single reasonable construction." *Id.* Further, "[a]bsent evidence of culpability or intent to deceive by delaying formal correction, a patent should not be invalidated based on an obvious administrative error." *Id.* (citing *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1331 (Fed. Cir.

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¹ In its response to proposed changes to the C.F.R. relating to handling of multiple dependent claims, the U.S. Patent and Trademark Office ("USPTO") clarified that it opposes allowing multiple dependent claims that depend on other multiple dependent claims because such claims are burdensome to its examiners. Specifically, the USPTO stated that in its experience "multiple dependent claims are significantly more difficult to search and evaluate than a plurality of single dependent claims. Multiple dependent claims that depend on other multiple dependent claims would be even more burdensome." 1-V Patent Office Rules and Practice, Rule 75 n.914 (citing 72 FR 46717, 46796 (August 21, 2007)). Thus, the import of the prohibition on allowing multiple dependent claims to depend on other multiple dependent claims is administrative in nature – *i.e.*, to reduce the burden on the USPTO.

2005)); see also Funai Elec. Co. v. Daewoo Elecs. Corp., No. C 04-01830 CRB, 2006 WL 6130993, at *9 (N.D. Cal. Mar. 1, 2006).

III. ARGUMENT

A. Defendants Admit that the Multiple Dependency Errors in Claims 32-40 are Obvious.

As Defendants state in their motion, the fact that Claims 32-40 are improper multiple dependent claims "is apparent from the face of the '558 patent." *See* Defendants' Memorandum of Law in Support of Motion to Dismiss Improper Multiple Dependent Claims 32-40 (Docket No. 21) ("Defendants' Mem.") at 6. Penn agrees with Defendants that the multiple dependency errors are obvious upon review of the claims themselves.

Defendants further state that these claim dependency errors "[do] not depend on claim construction, the details of the patent specification, the knowledge of a person of skill in the art, or an assessment of the prior art." *Id.* Penn agrees that the multiple dependency errors on the face of the patent can be appreciated without claim construction, the details of the patent specification, the knowledge of a person of ordinary skill in the art, or an assessment of the prior art. But Penn disagrees with the conclusion that Defendants draw from those facts.

Specifically, rather than requiring invalidation of the claims as Defendants allege, these facts show that the needed correction is obvious and can be made by the Court during claim construction.

Significantly, Defendants do not allege that these claim dependency errors have resulted in any confusion or prejudice to Defendants. Nor do Defendants allege any intent to deceive by delaying formal correction on behalf of Penn. These types of obvious errors are precisely the kind that may be corrected by the Court. *See, e.g., Hoffer*, 405 F.3d at 1331 (holding that "[a]bsent evidence of culpability or intent to deceive by delaying formal correction," "[w]hen a

harmless error in a patent is not subject to reasonable debate, it can be corrected by the court, as for other legal documents").

B. The Obvious Multiple Dependency Errors Are Easily Corrected.

As explained below, the dependency errors in the '558 patent result from mistakes made by each Penn and the USPTO. However the existence of the improper multiple dependent claims is obvious from the face of the patent, and the correction of the claims is obvious from a review of the file history.

After the U.S. Patent and Trademark Office ("USPTO") issued a notice of allowance in the application leading to the '558 patent, the applicants filed a Request for Continued Examination and submitted additional claims for prosecution.² The applicant included new Application Claims 53 to 68. As shown in the table below, ³ Application Claims 59 to 68 had multiple dependency errors.⁴ The examiner allowed the new claims without comment, and the patent issued with multiple dependency errors in Claims 32 to 40.⁵

When a patent issues, the USPTO is tasked with renumbering the claims so that the issued claims appear in proper and sequential order. This process also involves renumbering the claims found in the dependency statements of the issued dependent claims. When the '558 patent issued, the USPTO renumbered the claims, but made errors in renumbering the dependencies in issued Claims 33 to 36 and 40. For example, issued Claim 33 corresponds to application Claim 60, and application Claim 60 depends on Claims 53 to 59. If the USPTO had renumbered the dependency reference that appears in issued Claim 33 to correspond to

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² Krumplitsch Decl., Ex. A, '558 File history, Nov. 6, 2008 Amendment and Supplemental Information Disclosure Statement.

³ Application claim no. 68 resulted in issued claim 41, which is not asserted in this litigation. As such, it is not included in the chart.

⁴ Krumplitsch Decl., Ex. A, '558 File history, Nov. 6, 2008 Amendment and Supplemental Information Disclosure Statement

⁵ Krumplitsch Decl., Ex. B, '558 File history, May 4, 2009 Notice of Allowance.

⁶ MPEP § 1302.04; 37 C.F.R. § 1.126.

application claim 60, then issued Claim 33 would depend on Claims <u>26</u> to 32 (which in turn correspond to application claims 53 to 59). Instead, issued Claim 33 states that it depends on Claims <u>1</u> through 32. There are similar mistakes in issued Claims 34 through 36 and 40. There is no explanation for these modifications, and presumably these errors were made at the USPTO as part of the administrative process of renumbering the claims prior to issuance.

With its "chain of dependencies" diagram, Defendants attempt to portray Claims 32-40 as a hopeless tangle of multiple dependent claims. Defendants' Mem. at 2. As shown in the table below, however, the necessary corrections are straightforward. In short, the dependency references of these Claims 32-40 can simply be modified to exclude the other multiple dependent claims (*i.e.*, to exclude claims 28 and higher), and the dependency references of Claims 33-36 and 40 can be renumbered to correct the error made by the USPTO when the patent issued (*i.e.*, to start the dependency reference at claim 26 rather than claim 1).

App.	Application Claims	'558	Current '558 Claims	Corrected '558 Claims
Claim		Claim		
53	Independent claim	26	Independent claim	No revision necessary
54	Independent claim	27	Independent claim	No revision necessary
55	"the method according to claim 53 or 54"	28	"the method according to claim 26 or 27"	No revision necessary
56	"the method according to claim 53 or 54"	29	"the method according to claim 26 or 27"	No revision necessary
57	"the method according to claim 53 or 54"	30	"the method according to claim 26 or 27 "	No revision necessary
58	"the method according to claim 53 or 54"	31	"the method according to claim 26 or 27 "	No revision necessary
59	"the method according to any one of claims 53 to 58 "	32	"the method according to any one of claims 26 through 31 "	"the method according to any one of claims 26 through 27."
60	"the method according to any one of claims 53 to 59 "	33	"the method according to any one of claims 1 through 32"	"the method according to any one of claims 26 through 27 "
61	"the method according to any one of claims 53 to 60 "	34	"the method according to any one of claims 1 through 33"	"the method according to any one of claims 26 through 27"
62	"the method according to any one of claims 53 to 60 "	35	"the method according to any one of claims 1 through 33"	"the method according to any one of claims 26 through 27"
63	"the method according to any one of claims 53 to 62 "	36	"the method according to any one of claims 1 through 35"	"the method according to any one of claims 26 through 27"
64	"the method according to claim 63 "	37	"the method according to claim 36 "	No revision needed once claim 36 is revised
65	"the method according to claim 63 "	38	"the method according to claim 36 "	No revision needed once claim 36 is revised

66	"the method according to claim 63 "	39	"the method according to claim 36 "	No revision needed once claim 36 is revised
67	"the method according to any one of claims 53 to 66 "	40	"the method according to any one of claims 1 through 39"	"the method according to any one of claims 26 through 27 "

Claims 32-40 currently depend from several types of claims: (a) independent, (b) dependent, and (c) multiple dependent claims. Claims 33-40 depend from each of types (a), (b), and (c), while Claim 32 depends from types (a) and (c). For each of these claims, the dependency is in the alternative only, as required by 35 U.S.C. § 112, ¶ 5, and dependency references (a) and (b) (*i.e.*, to independent and dependent claims) are proper. The error under 35 U.S.C. § 112, ¶ 5 that Defendants complain of is dependency reference type (c) whereby claims 32-40 refer back to other multiple dependent claims. However, as Defendants make clear in their brief, the nature of this error is obvious, and, as shown in the chart above, the correction is equally as obvious—simply correct the dependency renumbering errors made by the USPTO and remove the multiple dependent claims from the dependency references, leaving only the existing references to independent claims.

Claims 32-36 and 40 currently contain the same "any one of" language, and refer to both multiple dependent and to independent or dependent claims. So, removing reference to the multiple dependent claims remedies the error under 35 U.S.C. § 112, ¶ 5 for each of these claims. Further, Claims 37-39 depend only on Claim 36. So, once the language of Claim 36 is modified to remedy the multiple dependency error, that error is also remedied in Claims 37-39, without requiring any modification to the language of Claims 37-39.

- C. The Court Can and Should Correct the Multiple Dependency Errors in Claims 32-40 during Claim Construction.
 - 1. <u>District Courts have the authority to correct obvious errors in patent language.</u>

Absent evidence of culpability or intent to deceive by delaying formal correction, an obvious error in a patent, the correction of which is not subject to reasonable debate, can be corrected by the court. *Intermec Techs. Corp.*, 811 F. Supp. 2d at 984; *Hoffer*, 405 F.3d at 1331.

Hoffer is illustrative. The patent at issue in that case contained a claim that, as written, depended on a non-existent claim. The error was obvious on the face of the patent, and an examination of the file history showed that the error arose when the examiner incorrectly numbered the claims after they were allowed. Hoffer, 405 F.3d at 1331. Rather than correct the obvious error, however, the district court found the claim indefinite. Hoffer v. Microsoft Corp., Case No. C01-20731 JW, 2003 U.S. Dist. LEXIS 26729, at *27-28 (N.D. Cal. Nov. 24, 2003) (stating that "it is not within the purview of the Court to correct typographical errors in an issued patent"). The Federal Circuit rejected the district court's conclusion, disagreeing that the district court lacked judicial power to make such a correction. 405 F.3d at 1331. The Federal Circuit stated:

Absent evidence of culpability or intent to deceive by delaying formal correction, a patent should not be invalidated based on an obvious administrative error. The defendants did not state that they were prejudiced, or even confused, by the error. The district court held that it has no authority to correct or ignore even a typographical error in a patent. That is inaccurate. When a harmless error in a patent is not subject to reasonable debate, it can be corrected by the court, as for other legal documents.

Id.

Here, as Defendants point out, "the fact that Claims 32-40 are improper multiple dependent claims is apparent from the face of the '558 patent." Defendants' Mem. at 6. As described above, this multiple dependency issue can be corrected via simple modifications to Claims 32-40. Further, these modifications are not subject to reasonable debate as the prosecution history does not suggest a different interpretation of the claims. As described above, Claims 32-40 were added late in the prosecution process, and contained the multiple dependency

errors when they were presented to the USPTO. As is evident from a review of the patent and file history, these multiple dependency errors were not caught by the examiner, and were further compounded by the USPTO's apparent renumbering error in the issued patent.

Finally, there is no evidence here to suggest culpability or intent to deceive during the prosecution of the '558 patent, nor have Defendants alleged any confusion or prejudice resulting from the claim dependency errors. Accordingly, the multiple dependency error in Claims 32-40 can and should be corrected by the Court.

2. <u>Pfizer v. Ranbaxy does not require that a multiple dependency issue that violates 35 U.S.C. § 112, ¶ 5 result in a finding of invalidity.</u>

Defendants cite *Pfizer*, *Inc. v. Ranbaxy Labs.*, *Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006) for the proposition that a claim that violates any of the requirements of 35 U.S.C. § 112 is invalid. *See* Defendants' Mem. at 4.⁷ *Pfizer*, however, dealt with §112, ¶ 4—not §112, ¶ 5. Even more significantly, *Pfizer* dealt with a claim error that could be corrected in two substantively different ways, which is not the situation in the instant case.

In Pfizer, the court was confronted with a dependent claim that was improperly drafted—it claimed subject matter for which there was no antecedent basis in the claim on which it depended. This is not allowable under 35 U.S.C. § 112, ¶ 4. The Federal Circuit noted that this appeared to be a drafting error, and could have been corrected in one of two ways—either by drafting the claim at issue as a dependent claim of a different claim (i.e., a broader claim), or by drafting the claim as an independent claim. Because there were multiple ways to correct the

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In addition to *Pfizer*, Defendants also cite to M.P.E.P. § 608.01(n), which states that examiners should "object to" multiple dependent claims which depend from other multiple dependent claims. Penn agrees that claims that violate 35 U.S.C. § 112, ¶ 5 should receive an objection from the USPTO. But, we are well beyond the stage where the response of the examiner per the M.P.E.P. is an issue. That ship has sailed; the examiner allowed the '558 patent to issue despite the multiple dependency error in Claims 32-40. As a result, we are now faced with determining how the district court should deal with this error. The M.P.E.P. does not offer guidance on this issue. Aside from *Pfizer* and M.P.E.P. § 608.01(n), Defendants do not cite to any other authority to support their claim that the multiple dependency error in Claims 32-40 render those claims invalid.

error, the Federal Circuit held that the district court could not re-write the claim in order to preserve its validity.

Pfizer is distinguishable from the situation at hand, though. In Pfizer, making a judgment as to how to re-write the claim that violated 35 U.S.C. \$ 112, \P 4 would have required the court to conduct claim differentiation analysis, and to make a judgment as to the preferred scope of the claim at issue. In other words, the Pfizer court was confronted with something more than an obvious error not subject to reasonable debate. Here, however, there is only one possible solution—to delete the erroneous references to multiple dependent claims. This is the type of obvious error that is within the power of the district court to correct.

3. The appropriate time to correct a multiple dependency error under 35 U.S.C. § 112, ¶ 5 is at claim construction.

Defendants' argument that district courts routinely decide the validity of patents under 35 U.S.C. § 101 (and/or issues of indefiniteness under 35 U.S.C. § 112) on motions to dismiss is inapposite. Validity under 35 U.S.C. § 101 and indefiniteness under 35 U.S.C. § 112 are not issues that district courts have the power to correct. Generally speaking, when faced with a patent claim that is fatally flawed under either of these theories, the district court must dismiss any infringement allegations stemming from that claim. But where, as here, the district court is confronted with an obvious error evident on the face of the patent, the court has the authority to correct the error, and does not need to resort to dismissing the claims.

Thus, instead of dismissing the claims, the court should make the necessary corrections to the language of the claims. The appropriate time to do so is at claim construction, not at the pleading stage. *See e.g.*, *CBT Flint Partners*, 654 F.3d at 1358-1359 (rejecting defendant's argument that correction of a claim must precede claim construction); *Cephalon, Inc. v. Watson*

Pharms., *Inc.*, 769 F. Supp. 2d 761, 769-770 (D. Del. 2011) (addressing claim correction at claim construction stage).

IV. CONCLUSION

For the foregoing reasons, Plaintiff The Trustees of the University of Pennsylvania respectfully requests that the Court deny Defendants' Motion to Dismiss in its entirety.

FINEMAN KREKSTEIN & HARRIS, P.C.

OF COUNSEL:

Jonathan G. Graves jgraves@cooley.com Cooley LLP One Freedom Square Reston Town Center 11951 Freedom Drive Reston, VA 20190 (703) 456-8000

DeAnna Allen dallen@cooley.com Cooley LLP 1299 Pennsylvania Ave, NW Suite 700 Washington, DC 20004 (202) 842-7896

Susan Krumplitsch skrumplitsch@cooley.com Cooley LLP 3175 Hanover Street Palo Alto, CA 94304 (650) 843-5000

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By: /s/ Jonathan G. Graves

Jonathan G. Graves

Andrew A. Chirls (No. 35422) Fineman Krekstein & Harris, P.C. Ten Penn Center 1801 Market Street, Suite 1100 Philadelphia, PA 19103 (215) 893-8715

Attorneys for Plaintiff
The Trustees of the University of Pennsylvania

CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was served on counsel for Defendants Eli Lilly and Company, ImClone LLC and Bristol Myers Squibb Company via electronic mail.

Dated: February 8, 2016 Respectfully submitted,

OF COUNSEL: Jonathan G. Graves jgraves@cooley.com Cooley LLP One Freedom Square Reston Town Center 11951 Freedom Drive Reston, VA 20190 (703) 456-8000

DeAnna Allen dallen@cooley.com Cooley LLP 1299 Pennsylvania Ave, NW Suite 700 Washington, DC 20004 (202) 842-7896

Susan Krumplitsch skrumplitsch@cooley.com Cooley LLP 3175 Hanover Street Palo Alto, CA 94304 (650) 843-5000 By: /s/ Jonathan G. Graves

Jonathan G. Graves

Andrew A. Chirls (No. 35422) Fineman Krekstein & Harris, P.C. 1801 Market Street, Suite 1100 Philadelphia, PA 19103

Attorneys for Plaintiff The Trustees of the University of Pennsylvania